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Patent
Attorney's Docket No. 000951-089

#24/Petition 1181

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	)	
	)	
Joseph B. PHIPPS	)	Group Art Unit: 3734
	)	
Application No.: 08/463,904	)	Examiner: M. Bockelman
	)	
Filed: June 5, 1995	)	
	)	
For: METHOD AND DEVICE FOR TRANSDERMAL ELECTROTRANSPORT DELIVERY OF FENTANYL AND SUFENTANIL	)	

PETITION UNDER 37 C.F.R. § 1.181 TO REVIEW NON-ENTRY OF AMENDMENT FILED UNDER 37 C.F.R. §1.116

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicant hereby respectfully petitions to have the non-entry of the Amendment and Declaration Under 37 C.F.R. §1.132 filed on August 3, 1998, as set forth in the Advisory Action dated August 18, 1998, reviewed and reversed.

To understand the present situation, a brief summary of the prosecution history of the present application is in order. More precisely, the present application was filed on June 5, 1995, and hence is entitled to a patent term that is the longer of 20 years from the filing date or 17 years from the date of issuance. On July 5, 1996, a first Official Action was mailed that 1) rejected some of the claims on formal grounds, 2) rejected claims 1, 4 and 7-18 as being anticipated by Phipps et al, U.S. Patent No. 5,423,739, 3) rejected claims 3-4 and 5-6 over the combination of the '739 patent and Phipps et al, U.S. Patent

No. 5,125,894, and 4) rejected all of the claims over the combination of Weaver et al, U.S. Patent No. 5,019,034, or Sibalis et al, U.S. Patent No. 4,878,892, in view of Levy et al, U.S. Patent No. 4,822,802.

An Amendment was filed on February 5, 1996, which made certain revisions to the specification, substantively amended independent claims 1 and 10, made additional amendments in several of the dependent claims and canceled claim 18 without prejudice or disclaimer. In the remarks, applicant explained the background and certain aspects of the invention by stating:

> The presently claimed invention relates to a method of delivering an analgesic drug selected from the group consisting of fentanyl salts and sufentanil salts through a body surface by electrotransport from an electrotransport delivery device having a donor reservoir containing an at least partially aqueous solution of a fentanyl salt or a sufentanil salt. As is known in the art, fentanyl and sufentanil are extremely potent analgesic drugs (fentanyl being approximately 100 times more potent than morphine and sufentanil being even more potent) whose administration to a patient must be carefully controlled. With passive transdermal patches, the analgesic drug was continuously delivered to the patient with the amount of drug in the patch being determined by the dosage to be administered. One of the drawbacks of passive transdermal patches is that there is a significant lag time required to achieve peak plasma levels. While electrotransport delivery devices can significantly reduce the lag time necessary to achieve peak plasma levels, it has been difficult to maintain a predictable transdermal electrotransport flux at a particular applied current level.
>
> The present invention addresses the significant challenge in the art and enables an essentially constant electrotransport flux to be obtained at an applied electrotransport current level. In particular, it has been found that by maintaining the concentration of a fentanyl salt in an aqueous solution in the donor reservoir at a level above about 11 mM or by maintaining the concentration above about 1.7 mM when the drug is a sufentanil salt, the electrotransport flux can be maintained at an essentially constant level substantially throughout the analgesic drug electrotransport delivery period wherein the analgesic drug is delivered through the body surface. In this

respect, it is important to understand that the defined relatively high concentration of fentanyl salt or sufentanil salt is maintained during the delivery period and that accordingly, delivery is terminated before the contents of the reservoir are depleted. By thus following the present invention, one can achieve a high level of predictability since the delivery of the drug is terminated before a significant decrease in the normalized flux occurs.

On March 10, 1997, a final Official Action was mailed. The Official Action withdrew the rejection on formal grounds, but again presented the prior art rejections set forth in the first Official Action. In response to the arguments presented in the prior Amendment, the Examiner took the position that applicant had not provided evidence to show that the teachings in the '739 and '894 patents would not lead to the claimed invention and indicated that the rejection based on the combination of Weaver et al or Sibalis et al in view of Levy et al, was proper because the claims "read" on other electrotransport techniques.

In response to the positions taken by the Examiner, a Declaration by the inventor, Dr. Phipps, was submitted on June 9, 1997. The Declaration explained in considerable detail the reasons why the teachings of cited documents would not lead to the invention in order to respond to the Examiner's position concerning the alleged absence of evidence. In addition, the Declaration explained the potency of the claimed drugs and the potential for abuse or misuse.

An Interview Summary form was mailed on June 26, 1998, stating that the after final submission had been received and on July 30, 1997, a new final Action was issued

restating the first combination as being Weaver et al or Sibalis et al each further in view of Levy et al and maintaining the rejection over the combination of the '739 and '894 patents.

On October 24, 1997, applicant filed an after final Amendment that revised the claims to recite that iontophoresis was the mechanism by which the defined drugs were administered and provided a copy of a publication that was noted as being missing by the Examiner. This amendment to the claims was simply to respond to the Examiner's position that evidence concerning other forms of electrotransport had not been provided and to make it clear that the invention related to the total drug delivery period.

Despite numerous telephonic inquiries, no action was taken on applicant's after final Amendment for over 5 months until a new final Action was mailed on April 2, 1998 (thereby requiring the submission of a Notice of Appeal with attendant petition for extension of time). The Action went into considerable detail essentially alleging that the claims did not correspond to the evidence and setting forth a new ground of rejection based on Haak et al, U.S. Patent No. 5,203,768, in view of the '894 patent and raising a number of new issues over the 16 page Action. For instance, on page 4 of the Action, the Examiner noted that he had changed his position slightly and that he now contended that the claims did not relate to the linear region of fentanyl delivery. In addition, despite the consistent arguments regarding the potency of the claimed drugs, the Examiner for the first time argued at the top of page 9 of the Action:

> Notwithstanding, neither applicant nor the prior art demonstrate if overdosing is even possible using the salt forms of fentanyl and sufentanil by passive transdermal application much less concentrations and amounts

> approaching dangerous levels. Why would one be concerned about overdosing in the range of 10 mM....

In order to narrow the issues for purposes of appeal and respond to the points raised in the extensive new final Action, applicant timely filed an Amendment and Submission of Declaration Under 37 C.F.R. §1.132 on August 3, 1998. This document amended the independent claims to recite the levels clearly showing the linear region of fentanyl delivery noted by the Examiner in the previous Action. Essentially, the two independent claims were amended to include the recitations found in original dependent claims 3 and 12, respectively. In addition, claims 2, 3, 4, 5, 6, 11, 12, 14 and 15 were canceled without prejudice or disclaimer. The effect of these amendments was clearly to reduce the issues on appeal without raising any new issues. A further Declaration by the inventor was also submitted which explained certain teachings of the prior art and two articles were provided to respond to the Examiner's new position that no evidence illustrating the dangers of the claimed drugs had been made of record.

In the Advisory Action dated August 18, 1998, the Examiner refused to enter the amendments to the claims. The Examiner did not contend that the amendments raised new issues or required further consideration and/or search, did not contend that they raised the issue of new matter, did not contend that they were not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal and did not contend that they presented additional claims without cancelling a corresponding number of finally rejected claims. Instead, the Examiner merely took the position that there was no convincing showing under 37 C.F.R. §116(b) and commented that because he had

twice reopened prosecution, there should be no reason for further amending since applicant has had sufficient opportunities to develop proper claim scope. The Examiner further indicated that while he had considered the Declaration, it did not overcome the rejections.

Applicant respectfully submits that the refusal to enter the Amendment based on the provisions of 37 C.F.R. §116(b) is improper in the present situation, particularly in view of the provisions of 37 C.F.R. §116(a). The relevant portions of these sections of the rules state:

> (a) After final rejection or action (§1.113) amendments may be made canceling claims or complying with any requirement of form which has been made. Amendments presenting rejected claims in better form for consideration on appeal may be admitted.
>
> (b) If amendments touching the merits of the application or patent under reexamination are presented after final rejection, or after appeal has been taken, or when such amendment might not otherwise be proper, they may be admitted upon showing of good and sufficient reasons why they are necessary and were not earlier presented.

As noted above, the amendments to the claims at issue unquestionably canceled a substantial number of claims and presented rejected claims in better form for appeal by incorporating the subject matter of original dependent claims into the independent claims. Moreover, in view of the admitted "changed position" by the Examiner set forth on page 4 of the Action, it can also be understood that claim amendment place the claims in better form for appeal. Therefore, applicant respectfully submits that the provisions of 37 C.F.R. §1.116(a) should be applied and that entry of the amendments to the claims are accordingly proper in all respects.

Even if the standards of 37 C.F.R. §1.116(b) are applied, the amendments to the claims are still proper. The Examiner's "changed position" precipitated the amendments to the claims. Indeed, such amendments were simply further instances of applicant's attempts to comply with the Examiner's requests throughout the prosecution of the present application. When the Examiner has requested information or has stated that no evidence exists, applicant has attempted to comply with the Examiner's requests. Similarly, when the Examiner questioned the claims in the Official Action, applicant responded by clarifying the scope of the claims by including the recitations of original dependent claims. Therefore, since the amendments to the claims were in direct response to the "changed position" by the Examiner, applicant respectfully maintains that even if the provisions of 37 C.F.R. §1.116(b) are applicable, the amendments to the claims at issue meet the "good and sufficient reasons" needed for entry of the amendments.

For the foregoing reasons, applicant respectfully petitions for review and reversal of the decision by the Examiner set forth in the Advisory Action dated August 18, 1998, which denied entry of the amendments to the claims requested in the response dated August 3, 1998.

Respectfully submitted,

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: October 2, 1998

By: Robert G. Mukai

Robert G. Mukai
Registration No. 28,531